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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/803,126	03/09/2001	Alan R. Brooks	15303-000310	8941

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	12

DATE MAILED: 10/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/803,126	BROOKS ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to an isolated polynucleotide encoding estrogen regulated myosin-related protein (MRP), expression cassette cloned in a vector, and a isolated host cell for the expression, are classified in class 536, subclass 23.1, class 435, subclasses 69.1, 320.1, 252.3 and 325^{+}.

II. Claims 12-15, drawn to an isolated MRP polypeptide, are classified in class 530, subclass 350.

III. Claim 16, drawn to an antibody against MRP, is classified in class 530, subclass 387.1.

IV. Claims 17-19, 21-23 and 25-26, drawn to a method of modulating the estrogen receptor-mediated estrogen effect in a mammalian cell by regulating the MSP expression, are classified in class 514, subclass 2, class 435, subclass 7.1, 69.1, 70.1 and 320.1, class 536, subclass 23.1, and class 424, subclass 546.

V. Claims 17 and 21, drawn to a method of modulating the estrogen receptor-mediated estrogen effect in a mammalian cell by regulating MSP protein activity, are classified in class 514, subclass 2, class 530, subclass 350, class 435, subclass 7.1, 69.1, 70.1 and 320.1, and class 424, subclass 546.

VI. Claims 17-26, drawn to a method of modulating the estrogen receptor-mediated estrogen effect in a non-human animal, i.e. a mammal, comprising regulation of MSP expression via an antisense therapy, are classified in class 514, subclass 2, class 530, subclass 350, class 435, subclass 7.1, 69.1, 70.1 and 320.1, class 536, subclass 23.1, class 424, subclass 546, and class 800, subclasses 14 and 286.

VII. Claims 27—28 and 31-32, drawn to a method of detecting the presence of estrogen signaling in a mammalian cell, are classified in class 514, subclass 2, class 530, subclass 350, class 435, subclass 7.1, 69.1, 70.1 and 320.1, class 536, subclass 23.1, class 424, subclasses 93.7 and 546.

VIII. Claims 27 and 29, drawn to a method of detecting the presence of estrogen signaling in a non-human animal, i.e. mammal, are classified in class 514, subclass 2, class 530, subclass 350, class 435, subclass 7.1, 69.1, 70.1 and 320.1, class 536, subclass 23.1, class 424, subclass 546, and class 800, subclasses 14 and 286.

IX. Claims 33-37, drawn to a method of identifying a compound capable of acting as a

estrogen receptor ligand, agonist or antagonist, comprising up-regulating MSP mRNA expression, are classified in class 436, subclass 501, class 435, subclasses 7.1, 69.1, 70.1 and 320.1, class 536, subclass 23.1, and class 424, subclass 546.

X. Claims 33 and 38-39, drawn to a method of identifying a compound capable of acting as a estrogen receptor ligand, agonist or antagonist, comprising up-regulating MSP protein level, are classified in class 436, subclass 501, class 514, subclass 2, class 435, subclasses 7.1, 69.1, 70.1 and 320.1, class 536, subclass 23.1, and class 424, subclass 546.

XI. Claims 33 and 38-39, drawn to a method of identifying a compound capable of acting as a estrogen receptor ligand, agonist or antagonist, comprising up-regulating MSP protein activity, are classified in class 436, subclass 501, class 514, subclass 2, class 435, subclasses 7.1, 69.1, 70.1 and 320.1, class 536, subclass 23.1, and class 424, subclass 546.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention II is drawn to polypeptide and Invention III to an antibody while Invention I is drawn to a polynucleotide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

In addition, Invention I is directed to polynucleotides that is classified in class 536, subclass 23.1, and/or to a cell into which polynucleotides is transferred and a vector where the polynucleotide is able to direct biosynthesis of the gene product, which process would have been searched in class 435 subclass 69.1. Invention III is directed to antibody that is classified in class 530, subclass 387.1. Thus, they acquire the different classification.

Invention II (polypeptide) and Invention III (antibody) are distinct from each other because of the materially different structures of the compounds claimed. Although antibody is belong to a types of polypeptide, antibody is glycosylated and its tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. Thus, the macromolecule of each invention would be expected to exhibit different physical and biochemical properties, and are capable of separate manufacture or use.

Invention I is related to Inventions IV, VI, VII, VIII and IX as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide can be immobilized on the DAN-microchip surface for genomic typing analysis, for example.

Invention I is unrelated to Invention V, X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the biological mechanism of polynucleotide directed transcription is distinct from that of protein mediated cellular functions and from that of detecting presence of protein.

Invention II is related to Inventions V, X and XI as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be use to raise an antibody against the polypeptide, for example.

Invention IV and Invention II are related as process of making and product made. Note that the method of Invention IV involves the expression of MSP polypeptide. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the polypeptide can be made by in vitro biosynthesis.

Invention II is unrelated to Inventions VI, VII, VIII and IX. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the biological mechanism of polynucleotide directed transcription is distinct from that of protein mediated cellular functions and from that of detecting presence of protein.

Invention III is unrelated to Inventions IV, V, VI, VII, VIII, IX, X and XI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the biological cellular mechanism and function of antibodies are distinct from those of polynucleotides and non-immunoglobulin polypeptides.

Inventions IV, V, VI, VII, VIII, IX, X, and XI are related as different and/or distinct methods, a method of modulating the estrogen receptor- mediated estrogen effect in a mammalian cell by regulating the MSP expression, a method of modulating the estrogen receptor- mediated estrogen effect in a mammalian cell by regulating MSP protein activity,

a method of modulating the estrogen receptor- mediated estrogen effect in a non-human animal, i.e. a mammal, comprising regulation of MSP expression via an antisense therapy, a method of detecting the presence of estrogen signaling in a mammalian cell, a method of detecting the presence of estrogen signaling in a non-human animal, i.e. mammal, a method of identifying a compound capable of acting as a estrogen receptor ligand, agonist or antagonist, comprising up-regulating MSP mRNA expression, a method of identifying a compound capable of acting as an estrogen receptor ligand, agonist or antagonist, comprising up-regulating MSP protein level, a method of identifying a compound capable of acting as an estrogen receptor ligand, agonist or antagonist, comprising up-regulating MSP protein activity, respectively. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper among the methods of Inventions IV – XI since they constitute patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art shown by their different classification, art recognized divergent subject matter, separate search, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

SWL

SWL
September 26, 2002

[illegible] Cochrane Carlson, Ph.D.

[illegible]EN COCHRANE CARLSON, PH.D
[illegible]MARY EXAMINER